



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

HP  
7/23/96

Applicant: J. Gregor Sutcliffe  
Serial No.: 08/116,873  
Filed: September 3, 1993  
For: SYNTHETIC POLYPEPTIDES CORRESPONDING  
TO PORTIONS OF PROTEINOIDS  
TRANSLATED FROM BRAIN-SPECIFIC mRNAs,  
RECEPTORS, METHODS AND DIAGNOSTICS  
USING THE SAME  
Examiner: L. Schriener

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Group Art Unit 1813  
PATENT

APPELLANT'S REPLY BRIEF ON APPEAL

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

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LCO  
9/27/96

This Reply Brief is provided to assist the Board in further assessing the issues of this appeal, particularly in light of the Answer's newly applied reliance upon Amgen v. Chugai, 19 USPQ2d 1017 (Fed. Cir. 1991), hereinafter Amgen, and assertions as to a lack of a recitation of function of a claimed DNA.

The Amgen decision portion with which the Answer has concerned itself has to do with conception of a DNA sequence that encoded the protein erythropoietin (EPO). EPO is a red blood cell-stimulating protein that is 165 amino acid residues in length.

As is well known, the genetic code is largely redundant, with there being at least two DNA codons that encode most of the amino acid residues. Some amino acid residues are encoded by six different codons, e.g. serine, arginine and leucine. Others such as valine and alanine are encoded by four condons, whereas still other residues are encoded by only one condon, e.g., methionine and tryptophan.

Although there are many more amino acid residues encoded by more than two codons than there are residues encoded by one codon, a very conservative estimate of an average of two codons per residue can be made. Using that very conservative estimate, it is easily seen that the number of DNAs that could encode the same EPO molecule is equal to  $2^{165}$ . It is submitted that  $2^{165}$  is such an unimaginably large number that that number of separate EPO-encoding DNAs cannot be conceived of by an inventor, as was found by the Court in Amgen.

The parallel from Amgen to the present situation does not, however, follow. The present claims are not directed to any DNA that encodes a specific product as in Amgen. Rather, these claims are directed to the specific gene that encodes a specific product in a given mammal.

That number of genes can be conceived of. The application teaches how to obtain those genes. The art of record shows that others of skill in this art have understood the language used here and have been able to obtain their own genes, while reporting that they have relied-on Dr. Sutcliffe's published disclosures that are present in this application.

The Answer also asserts that the functions of the DNAs (or mRNAs) as claimed have not been set forth. Counsel's review of each of the independent claims on appeal indicates that each DNA is recited to be "complementary" to a messenger RNA, and that that messenger RNA "encodes" a material that is "neuroactive". It is submitted that no further function is needed in a claim. Indeed, one does not look to the claims to find out how to practice the invention, but to the specification. In re Johnson and Farnham, 194 USPQ 187, 195 (CCPA 1977). The art of record

and that offered provide ample evidence that skilled workers understand the function of the DNAs of these claims.

It is therefore again submitted that these rejections should be reversed.

Respectfully submitted,

By   
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Enclosure  
Request for Oral Hearing and Fee

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CERTIFICATE OF MAILING

I hereby certify that this Appellant's Reply Brief on Appeal, in triplicate, and Request for Oral Hearing are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on June 26, 1996.

  
Edward P. Gamson